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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/933,767	08/22/2001	Jian Ni	PZ007P2	7025
22195	7590	07/20/2004	EXAMINER	
HUMAN GENOME SCIENCES INC INTELLECTUAL PROPERTY DEPT. 14200 SHADY GROVE ROAD ROCKVILLE, MD 20850			SISSON, BRADLEY L	
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 07/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/933,767

Applicant(s)

NI ET AL.

Examiner

Bradley L. Sisson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Election/Restrictions

- I. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-10, 14-15, and 21, drawn to isolated nucleic acid molecule (claims 1-6) a gene (claim 21), recombinant vector (claim 7), recombinant host cell (claims 9-10 and 14), method of making recombinant host cell (claim 8), and method of making polypeptide (claim 15), classified in class 435, subclass 69.1, 252.3, 320.1; and class 536, subclass 23.5.
 - II. Claims 11-12 and 16, drawn to isolated polypeptide, classified in class 530, subclass 350.
 - III. Claim 13, drawn to an isolated antibody, classified in class 530, subclass 387.
 - IV. Claim 17, drawn to a method of preventing, treating, or ameliorating a medical condition using either a polypeptide or a polynucleotide, classified in class 514, subclass 2 and 44.
 - V. Claim 18, drawn to a method of diagnosing a pathological condition, classified in class 435, subclass 6.
 - VI. Claim 19, drawn to a method of diagnosing a pathological condition or a susceptibility to a pathological condition, classified in class 436, subclass 501.
 - VII. Claim 20, drawn to a method of identifying a binding partner to a polypeptide, classified in class 436, subclass 501.
 - VIII. Claim 22, drawn to a method of identifying an activity in a biological assay, classified in class 435, subclass 4.

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IX. Claim 23, drawn to a binding partner to a polypeptide, classified in class 530, subclass 350.

2. The inventions are distinct, each from the other because of the following reasons:

3. Inventions I and II are patentably distinct in structure and physicochemical properties.

Invention I is drawn to nucleic acids whereas invention II is drawn to proteins. Because nucleic acids are composed of nucleotides and proteins are composed of amino acids, the inventions have different structural and functional properties. Furthermore, the products are utilized in different methodologies, such that nucleic acids may be utilized in hybridization assays, while proteins may be utilized in ligand binding assays or to generate antibodies. Synthesis of the proteins of invention II do not require the particular products of the nucleic acids of invention I since the proteins of invention II can be isolated from natural sources or chemically synthesized.

4. Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the nucleic acids of invention I are not required to make the antibodies of invention III. Furthermore, the different inventions are not disclosed as capable of use together and have different functions and have different physical and structural properties.

5. Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P.

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§ 806.05(h)). In the instant case, the nucleic acids of invention I can be used in a materially different process, such as for synthesizing nucleic acids or proteins, or for diagnostic methods.

6. Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P.

§ 806.05(h)). In the instant case, the nucleic acids of invention I can be used in a materially different process, such as for synthesizing nucleic acids or proteins, or for therapeutic methods.

7. Inventions I and VI, I and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the nucleic acids of invention I are not required to practice the methods of inventions VI or VII.

8. Inventions I and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P.

§ 806.05(h)). In the instant case, the nucleic acids of invention I can be used in a materially different process, such as for synthesizing nucleic acids, or for therapeutic or diagnostic methods.

9. Inventions I and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the nucleic acids of invention I are structurally and functionally distinct from the binding partners of

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invention IX. Furthermore, the different inventions are not disclosed as capable of use together and are utilized in different methods, such that the nucleic acids of invention I may be used in methods of diagnosis and the binding partners of invention IX may be used in therapeutic methods.

10. Inventions II and III are patentably distinct in structure in that the proteins of invention II have a different amino acid sequence and 3-dimensional structure as compared to the antibodies of invention III. Furthermore, the products of invention II and III are utilized in different methodologies, such that the proteins may be utilized in ligand binding assays and the antibodies may be used in therapeutic methods. Synthesis of the antibodies of invention III does not require the particular products of the proteins of invention II since the antibodies of invention III can be isolated from natural sources.

11. Inventions II and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the proteins of invention II are not required to practice the methods of inventions IV or V.

12. Inventions II and IV, II and VI and II and VII, and II and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the proteins of invention II can be used in a materially different process, such as for generating antibodies.

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13. Inventions II and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different functions and different modes of operation. Further, the proteins of invention II and the binding partners of invention IX are structurally distinct.

14. Inventions III and IV, III and V, and III and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are not disclosed as capable of use together because the antibodies of invention III are not required to practice the methods of invention IV, V, or VII.

15. Inventions III and VI, and III and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the antibodies of invention III can be used in a materially different process, such as for therapeutic uses.

16. Inventions III and VII are drawn to patentably distinct inventions. Invention III is drawn to an antibody, whereas invention VII is generically drawn to any compound, which binds the stated proteins. Antibodies are composed of a specific amino acid sequence and have a unique structure and defined interaction with a protein, whereas the compounds of invention VII include any type of chemical moiety having any structural or functional properties.

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17. Inventions III and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P.

§ 806.05(h)). In the instant case, the antibodies of invention III can be used in a materially different process, such as for detecting or isolating proteins.

18. Inventions IV, V, VI, VII, and VIII are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

In the instant case, the different inventions are drawn to distinct methods, each requiring different reagents, involving different method steps and having different objectives.

19. Inventions IX and IV, IX and V, IX and VI, IX and VIII are unrelated to each other.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions In the instant case, the different inventions are not disclosed as capable of use together because the binding partner of invention IX is not required to practice the methods of inventions IV, V, VI, or VIII.

20. Inventions VII and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P.

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§ 806.05(h)). In the instant case, the binding partners of invention IX can be used in a materially different process, such as for

Sequence Election Requirement Applicable to All Groups

21. Each invention detailed above reads on a patentably distinct invention drawn to distinct sequences. The sequences are patentably distinct because they are unrelated sequences, and a further restriction is applied to each invention. For an elected invention drawn to a nucleic acid or amino acid sequences, Applicants must further elect a single nucleic acid or amino acid sequence. For example, if Applicant elects invention I, Applicant must further elect a single nucleic acid sequence “X”, a single nucleic acid encoding protein “Y” and a single cDNA contained in a clone “Z”.

22. It is noted that nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.14. Applicant is advised that this is a restriction requirement and should **not be construed as an election of species.**

23. Because these inventions are distinct for the reasons given above and have acquired a different status in the art as demonstrated by their different classification and recognized divergent subject matter and because inventions I-IX require different searches that are not co-

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extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

24. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

25. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

26. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

27. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product

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claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

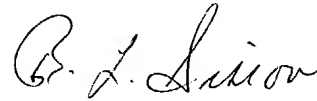
28. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

29. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

30. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "B. L. Sisson". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
19 July 2004